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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,124	07/23/2003	Steven F. Dobrowolski	2428.011	2364
7590 12/20/2005 HESLIN, ROTHENBERG, FARLEY & MESITI, P.C. 5 Columbia Circle New York, NY 12203			EXAMINER MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/625,124	Applicant(s) DOBROWOLSKI ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Claims 2, 4-13, and 15-24 are subject to a restriction since these claims are not considered to recite a proper genus/Markush group.

Specifically, claim 2 recites methods for detecting distinct mutations in the biotinidase gene, wherein the mutations are selected from the group consisting of G98:d7i3, Q456H, R538C, D444H, and A171T. Each of these mutations occurs at a distinct nucleotide position in the biotinidase gene and has a distinct effect on the activity of the product encoded by the biotinidase gene. Given the differences in structure and function, the Markush group set forth in claim 2 is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement.

Further, claims 4-13 and 15-24 recite methods requiring the use of distinct nucleic acid primer pairs, detection probes, and anchor probes, wherein the forward primer of the primer pair is selected from SEQ ID NO: 4-8, the reverse primer of the primer pair is selected from SEQ ID NO: 9-13, the detection probe is selected from SEQ ID NO: 19-23, and the anchor probe is selected from SEQ ID NO: 14-18. Each of the primers and probes consists of a distinct nucleic acid sequence, has a different melting point, and binds to a different nucleic acid sequence, and thereby has a different biological function. Given the differences in structure and function, the Markush group set forth in claims 4-13 and 15-24 is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement.

A sequence search and non-patent literature search of these mutations and primer and probes sequences would not be co-extensive with one another. For

example, a search for methods which detect the G98:d7i3 mutation would not be co-extensive with a search for methods which detect the Q456H mutation. Similarly, a search for the nucleic acid sequence of SEQ ID NO: 4 would not be coextensive with a search of the nucleic acid sequence of SEQ ID NO: 5. Further, a reference which renders obvious or non-novel the primer of SEQ ID NO: 4 would not also necessarily render obvious or non-novel the primer of SEQ ID NO: 5. Similarly, a finding that the primer of SEQ ID NO: 4 is novel and unobvious over the prior art would not necessarily extend to a finding that the primer of SEQ ID NO: 5 is also novel and unobvious over the prior art. Accordingly, a search of more than one of the mutations and more than one of the combinations of primers and probes presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences.

Therefore, Applicants are required to elect:

- a) one mutation selected from the group consisting of G98:d7i3, Q456H, R538C, D444H, and A171T
- b) one set of primers, one detection probe and one anchor probe, corresponding to the elected mutation. Note that this is not a species election.

Claims 1, 3 and 14 link the individual mutations and sequences of claims 2, 4-13 and 15-24, each mutation and sequence comprising a distinct invention as outlined above. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s)

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depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach


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the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
December 12, 2005


CARLA J. MYERS
PRIMARY EXAMINER